MAY - 9 2003

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K021230

3 510(k) Summary

Date:	5/7/2003
Submitter:	Medical Predictive Science Corporation 2246 Ivy Rd, Suite 17 Charlottesville, VA 22903
Contact:	William E King Project Manager (800) 394 1625 (434) 951 2980 (Direct) (434) 951 0226 (FAX) wking@rals.com
Trade Name: Common Name:	HERO HRV Analysis System
Classification Name: Classification Number:	Electrocardiograph 21CFR 870.2340 74DPS, Class II
Predicate Device:	K991786 GE Marquette MARS Unity Workstation with Heart Rate Variability (HRV) Option
Device Description:	HERO is comprised of several off-the-shelf Personal Computers (PC's) capable of acquiring, storing, analyzing, and reporting ECG data from the cardiac monitoring real-time network. Data is acquired, stored, analyzed, and displayed on a Bedside Monitoring Station (BMS) located near each patient. Demographic data is entered on a Central Monitoring Station (CMS). Results of the analyses are reported by both the CMS and the BMS. The analysis algorithms identify Heart Rate Variability (HRV) patterns that reflect transient decelerations and/or reduced baseline variability.

Intended Use:	HERO is intended to acquire, store, analyze, and report on ECG data collected from infants. HERO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment. HERO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HERO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate. HERO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis. The specialized HRV measurements produced by HERO have not been approved by the FDA for any specific clinical diagnosis. HERO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.
Technology:	Microprocessor based system.
Test Summary:	HERO software was tested under software validation procedures developed in accordance with the *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* and the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* published by the FDA. HERO hardware is UL 2601-1 (standard for Medical Electrical Equipment) tested and certified, and meets appropriate requirements for the intended environment.
Conclusion:	HERO has a similar intended use as the predicate device. HERO raises no new questions of safety or efficacy when compared with the predicate device. Therefore, HERO is judged substantially equivalent to the MARS Unity Workstation with Heart Rate Variability (HRV) Option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Medical Predictive Science Corporation
c/o Mr. William E. King
Project Manager
2300 Commonwealth Drive
Charlottesville, VA 22901

Re: K021230
Trade Name: HERO
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 7, 2003
Received: February 10, 2003

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Indications for Use Statement

510(k) Number (if known): K021230.
Device Name: HERO

Indications for Use:

HERO is intended to acquire, store, analyze, and report on ECG data collected from infants. HERO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment.

HERO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HERO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate.

HERO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The specialized HRV measurements produced by HERO have not been approved by the FDA for any specific clinical diagnosis.

HERO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021230